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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,694	NAJAFI ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,17-31,33-40,44,48-58,60-63 and 65-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31* is/are allowed.

6)☒ Claim(s) *1-14,17-30,33-40,44,48-58,60-63,65 and 67-72* is/are rejected.

7)☒ Claim(s) *66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/6/07 has been entered.

Drawings

The drawings were received on 6/6/07. These drawings are accepted.

Claim Objections

Claims 60-62 are objected to because of the following informalities:

On line 2 of each of claims 60 and 61, "the pacing/ICD" should be replaced with " a pacing/ICD".

On line 3 of claim 61, "the external" should be replaced with "an external".

On line 3 of claim 62, "the pacing/ICD" should be replace with "a pacing/ICD". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 6, 9, 11, 12, 17, 19, 21, 23, 25, 27, 29, 33, 34, 37, 38, 44, 48, 57, 60-63, and 68-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites, "means adapted for clamping said implantable device to the septum, said at least one sensing device being implantable so that . . . a larger portion of said implantable sensing device is located in the right side of the heart and a smaller portion of said implantable sensing device is located in the left side of the heart and includes the at least one sensor, said clamping means of the anchoring mechanism comprising said smaller and larger portions of said implantable sensing device." The original disclosure lacks any description of the means adapted for clamping comprising the smaller and larger portions of the implantable sensing device. The means adapted for clamping is merely described as an umbrella structure 14 shown in figure 5 which may be folded inside a catheter for delivery and expanded for implantation (see figure 5; p. 13 of the specification). While the specification states that a majority of the implantable sensing device is located in the right side of the heart with minimum protrusion in the left side of the heart to reduce thrombogenicity, the specification contains no description of the umbrella structure or means adapted for clamping

comprising the (larger) portion of the implantable sensing device in the right side of the heart or the (smaller) portion of the implantable sensing device in the left side of the heart.

Claim 44 further recites, "said smaller and larger portions of said anchoring mechanism comprise two umbrella-shaped anchors". Again, the original disclosure contains no written descriptions of the means adapted for clamping or umbrella structure having such smaller and larger portions. In fact, in the device shown in figure 5, the two portions are shown as being about the same size. Furthermore, claim 44 depends on claim 1 which recites the smaller and larger portions as smaller and larger portions of the implantable sensing device, rather than of the anchoring mechanism. The specification provides no written description of the smaller and larger portions of the implantable sensing device as comprising the anchors.

Claims 63 and 68 recite, "wherein said readout device and said pacing/ICD unit perform at least one function of interrogation or powering of said at least one sensing device". The original disclosure fails to provide written support for the pacing/ICD unit powering the at least one sensing device, as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 44, 57 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,409,674 to Brockway et al. Brockway discloses a system for monitoring at least one physiological parameter for diagnosis of congestive heart failure within a patient, the system comprising at least one sensing device 305 adapted to be implanted in a cavity of the patient's cardiovascular system. The sensing device comprises an anchoring mechanism and at least one sensor (see entire document, especially figs. 1, 3A-3D; col. 8, line 10-col. 9, line 42 of Brockway). The anchoring mechanism comprises a portion capable of passing through a septum of a heart, means adapted for opening on at least one side of the septum, and means adapted for clamping said implantable device to the septum, wherein the stabilizer 312A-D is both adapted to open on at least one side of the septum or other body part and is adapted for clamping the implantable device to the septum or other body part in conjunction with the housing 300 (see entire document, especially figs. 3A-D; col. 8, lines 38-58 of Brockway). A non-implantable readout device is not adapted to be implanted in the patient and comprises at least one inductor coil having telemetric means for at least one of electromagnetic telecommunication and electromagnetic wireless powering of the sensing device through the coil (see entire document, especially col. 9, line 45-col. 10, line 26 of Brockway).

As to the language, "at least one sensing device being implantable so that said portion of the anchoring mechanism passes through the septum, and, to minimize risk of thrombogenicity, a larger portion of said implantable sensing device is located in the right side of the heard and a smaller portion of said implantable sensing device is

located in the left side of the heart and includes the at least one sensor", and any other language regarding the location of the sensing device or parts thereof with respect to the heart, septum, or other body part, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art since Brockway, as modified, teaches all of the claimed structural limitations and their recited relationships. The device of Brockway, as modified, can certainly be placed or implanted in such a way as to fulfill the recited intended use of the claimed invention. For example, the device of Brockway may be implanted such that the housing passes through the septum and the stabilizers 312D extend on one side of the septum or on opposite sides of the septum to hold the device in place, such that a larger part of the device is located in the right side of the heart and a smaller portion, including the sensor, is located in the left side of the heart.

The language "means adapted for opening on at least one side of the septum" and "means adapted for clamping said implantable device to the septum" fulfill the 3-prong analysis set forth in MPEP § 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. The corresponding structure for both means appears to be the umbrella structure shown in figure 5 and described on p. 13 of the instant specification. The stabilizer and housing of Brockway, as shown in figures 3A-D of Brockway is considered to be an equivalent of the applicant's means for opening and means for clamping since one of ordinary skill in the art would have recognized the interchangeability of the stabilizer and housing of Brockway for the corresponding elements shown in the instant specification. Further, the stabilizer and housing of Brockway performs or is capable of

performing the identical function specified in the claim in substantially the same way and produces substantially the same results as the corresponding element disclosed in the specification.

Regarding claims 5 and 6, the sensing device includes a battery, and the battery is rechargeable using wireless means (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway).

Regarding claims 9 and 23, the at least one physiological parameter includes pressure (see entire document, especially col. 7, lines 12-27 of Brockway).

Regarding claims 11 and 25, the applicants should note that the type of pressure sensed, as listed in claim 11, are merely a result of the location of the implantation of the sensing device. Therefore, the pressure types are merely "intended use" language, being reliant upon the intended use, since the intended location of the implantation is intended use. This language cannot be relied upon to define over the prior art, since the prior art teaches all of the claimed structural limitations and their recited relationships. The device of Brockway, as modified, is certainly capable of being implanted in such a location so as to monitor or sense the listed pressures. Additionally, the sensing device may be located in any one of the chambers of the heart such that right or left atrial or ventricular pressure may be sensed (see entire document, especially col. 7, lines 14-37 of Brockway).

Regarding claim 12, the system calculates the change of pressure over time (dp/dt) (see entire document, especially col. 1, lines 30-55; col. 9, lines 33-41 of Brockway).

Regarding claim 19, a passive scheme is used to couple the sensing device and readout device (see entire document, especially col. 9, line 64-col. 10, line 25 of Brockway).

Regarding claim 21, an active scheme is used to couple the sensing device and readout device, in that the readout device must be actively brought into the vicinity of the sensing device in order to enable wireless powering and/or communication between the readout device and sensing device (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway).

Regarding claims 27 and 29, the applicant should note that the intended use of the invention cannot be relied upon to define over the prior art since the prior art teaches all of the claimed structural elements and their recited relationships. The system of Brockway may certainly be used for disease management or treatment, for example (see entire document, especially col. 14, lines 37-40 of Brockway), or portable or ambulatory monitoring.

Regarding claims 37 and 38, the sensing device 105 is implanted using a minimally invasive outpatient technique or catheter delivery method (see entire document, especially col. 11, line 65-col. 13, line 54 of Brockway).

Regarding claim 44, the smaller and larger portions of the anchoring mechanism comprise two umbrella-shaped anchors adapted to be disposed on opposite sides of the atrial septum (see entire document, especially fig. 3D of Brockway).

Regarding claim 57, the sensing device is augmented with at least a pacing device, voltage source or current source (see entire document, especially figs. 4 & 5, col. 9, line 64-col. 10, line 14of Brockway)

Regarding claim 69, at least a portion of the implantable sensing device is coated with at least one layer of coating material (see entire document, especially col. 8, lines 34-36 of Brockway).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 7, 8, 20, 22, 24, 26, 28, 30, 39, 40, 58 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,886,064 to Strandberg in view of US Patent No. 6,409,6674 to Brockway et al. Strandberg teaches a system for monitoring at least one physiological parameter comprising at least one sensing device 6, 7 adapted to be implanted in the body, such as in a cavity of the patient's cardiovascular system. The sensor has optional electronic components (see entire document, especially figs. 1 & 2; col. 2, lines 34-42 and lines 50-69 of Strandberg). The system is part of a closed-loop pacing/ICD tuning mechanism comprising a pacing/ICD unit 1. Data from the at least one sensing device is sent to the pacing/ICD unit for tailoring the pacing/ICD function (see entire document, especially col. 3, lines 2-13 of

Strandberg). The sensing device is directly interrogated by the pacing/ICD unit (see entire document, especially col. 3, lines 3-13 of Strandberg). Strandberg lacks a non-implantable readout device.

However, Brockway teaches a system for monitoring at least one physiological parameter, comprising at least one implantable sensing device 105 and a non-implantable readout device, each of the sensing device and the readout device comprising at least one inductor coil allowing electromagnetic telecommunication and electromagnetic wireless powering of the sensing device through the at least one inductor coil (see entire document, especially col. 9, line 45-col. 10, line 25 of Brockway). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the arrangement for powering the sensing device of Brockway in place of that of Strandberg, as it would merely be the substitution of one known means for powering the sensor for another, to yield the predictable result of a powered sensor. Furthermore, Brockway teaches data transmission from the sensing device to the readout device for further recording and analysis of the measured physiological parameter (see entire document, especially col. 7, line 42-col. 8, line 7 of Brockway). Therefore, it would further have been obvious to one of ordinary skill in the art at the time of invention to apply the technique of data communication from an implanted sensor to an external readout device for further analysis as taught by Brockway to improve the system of Strandberg for the predictable result of enabling further recording and analysis of the measured physiological signals.

As to the language "for treatment of congestive heart failure within a patient" and "to be implanted in a cavity of the patient's cardiovascular system", the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Strandberg, as modified, teaches all of the claimed structural elements and their recited relationships. The system of Strandberg, as modified, is certainly capable of being used for treatment of CHF and the sensing device of Strandberg, as modified, is certainly capable of being implanted in such a cavity.

Regarding claims 7 and 8, the sensing device includes a battery, and the battery is rechargeable using wireless means (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway).

Regarding claim 20, a passive scheme is used to couple the sensing device and readout device (see entire document, especially col. 9, line 64-col. 10, line 25 of Brockway).

Regarding claim 22, an active scheme is used to couple the sensing device and readout device, in that the readout device must be actively brought into the vicinity of the sensing device in order to enable wireless powering and/or communication between the readout device and sensing device (see entire document, especially col. 9, line 64-col. 10, line 14 of Brockway).

Regarding claim 24, the physiologic parameter includes at least temperature (see entire document, especially col. 2, lines 50-52 of Strandberg).

Regarding claim 26, the location of implantation is merely "intended use" language which cannot be relied upon to define over the prior art since Strandberg, as modified, teaches all of the claimed structural limitations and their recited relationships. The at least one sensing device of Strandberg, as modified, is certainly capable of implantation in any of the locations listed in claim 26.

Regarding claims 28 and 30, the applicant should note that the intended use of the invention cannot be relied upon to define over the prior art since the prior art teaches all of the claimed structural elements and their recited relationships. The system of Strandberg, as modified, is certainly capable of being used for disease management, pacing adjustments, or portable or ambulatory monitoring (see entirety of both documents).

Regarding claims 39 and 40, the implantable sensing device is configured for implantation using a minimally invasive outpatient technique, wherein the sensing device of Strandberg is certainly of a size and shape to be implanted using a catheter (see entire document of Strandberg).

Regarding claim 58, the at least one sensing device is augmented with at least one actuator in the form of a probe, wherein the second sensing device is a probe (see entire document, especially fig. 2; col. 2, lines 50-69 of Strandberg).

Regarding claim 65, at least one sensing device is directly interrogated by the pacing/ICD unit (see entire document, especially col. 3, lines 1-13 of Strandberg).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway, as applied to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 44, 57 and 69 above, and further in view of US Patent No. 6,120,457 to Coombes et al. Brockway describes the pressure sensor as being, in one embodiment, resistive, rather than capacitive (see entire document, especially col. 9, lines 30-42 of Brockway). However, Coombes teaches that an implantable pressure sensor may be capacitive or resistive (see entire document, especially col. 1, lines 21-30 of Coombes). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a capacitive sensor in place of the resistive sensor of Brockway since Coombes teaches capacitive and resistive pressure sensors to be functionally equivalent.

Claims 3, 17, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway, as applied to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 44, 57 and 69 above, and further in view of US Patent No. 4,114,606 to Seylar. Brockway is silent as to the details of the scheme of inductive powering/communication between the sensing device and readout device. However, Seylar discloses inductive coupling between an implanted capacitive pressure sensor device and an external readout device wherein a resonant scheme is employed (see entire document, especially fig. 3; col. 3, line 61-col. 4, line 8; col. 4, line 30-col. 6, line 17 of Seylar). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the scheme of Seylar as that of Brockway, since Brockway teaches using an implantable sensing device to sense pressure and an external readout

device inductively coupled to the sensing device, and Seylar describes an appropriate means for coupling such devices. Alternatively it would have been obvious to one of ordinary skill in the art to use the type of system described by Seylar to sense pressure and transmit information in place of that of Brockway, as it would merely be the substitution of one known means for sensing pressure within a body and transmitting the information for another for the predictable result of transmitting measured pressure data.

Regarding claims 33 and 34, the readout device includes a barometric pressure sensor, wherein the barometric pressure sensor is adapted to compensate for variations in atmospheric pressure (see entire document, especially col. 7, lines 40-58 of Seylar)

Claims 4, 10, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strandberg in view of Brockway, as applied to claims 2, 7, 8, 20, 22, 24, 26, 28, 30, 39, 40, 58, and 65 above, and further in view of US Patent No. 4,566,456 to Koning et al. Strandberg, as modified, lacks a capacitive sensor. However, Koning teaches using the measurements of an implanted capacitive pressure sensor 24 to adjust the pacing of a pacing/ICD unit (see entire document, especially col. 5, lines 1-32; col. 6, lines 16-22 of Koning). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a pressure sensor in place of the temperature or motion sensor of Strandberg, as modified, wherein such sensor is implanted in the appropriate location, since it would merely be the substitution of one

known sensor for controlling a pacing parameter for another for the predictable result of controlling a pacemaker or pacing/ICD unit based on a sensor measurement.

Regarding claim 13, the at least one sensing device is adapted to be implanted so as to measure any of the pressures listed in claim 13, wherein the type of pressure measured is merely a function of the location of the sensor, and the location of the sensor is "intended use" language. The applicants cannot rely upon this intended use language to define over Strandberg, as modified, since the prior art teaches all of the claimed structural limitations and their recited relationships. The sensing device of Strandberg, as modified, is capable of being placed in any location of the heart suitable for measuring pressure.

Regarding claim 14, the system calculates the change of pressure over time (dp/dt; coll. 5, lines 33-45; col. 6, lines 7-16 of Koning).

Claims 18, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strandberg in view of Brockway and Koning, as applied to claims 4, 10, 13, and 14 above, and further in view of US Patent No. 4,114,606 to Seylar. Strandberg, as modified is silent as to the details of the scheme of inductive powering/communication between the sensing device and readout device. However, Seylar discloses inductive coupling between an implanted capacitive pressure sensor device and an external readout device wherein a resonant scheme is employed (see entire document, especially fig. 3; col. 3, line 61-col. 4, line 8; col. 4, line 30-col. 6, line 17 of Seylar). Therefore, it would have been obvious to one of ordinary skill in the art at

the time of invention to use the scheme of Seylar as that of Brockway, since Brockway teaches using an implantable sensing device to sense pressure and an external readout device inductively coupled to the sensing device, and Seylar describes an appropriate means for coupling such devices. Alternatively it would have been obvious to one of ordinary skill in the art to use the type of system described by Seylar to sense pressure and transmit information in place of that of Brockway, as it would merely be the substitution of one known means for sensing pressure within a body and transmitting the information for another for the predictable result of transmitting measured pressure data.

Regarding claims 35 and 36, the readout device includes a barometric pressure sensor, wherein the barometric pressure sensor is adapted to compensate for variations in atmospheric pressure (see entire document, especially col. 7, lines 40-58 of Seylar)

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway, as applied to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 44, 57 and 69 above, and further in view of US Patent No. 6,636,769 to Govari et al. Brockway teaches the anchoring mechanism may be made form a memory metal (see entire document, especially col. 8, lines 47-49 of Brockway), but is silent as to the specific metal used. However, Govari teaches an implantable sensor having an anchoring mechanism made from a memory metal such as nitinol (see entire document, especially col. 6, lines 43-45 of Govari). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use nitinol as the material for the anchoring

mechanism of Brockway, since Brockway teaches using an anchoring mechanism, and Govari teaches nitinol as an appropriate memory metal for such an anchoring mechanism.

Claim 49-55 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strandberg in view of Brockway, as applied to claims 2, 7, 8, 20, 22, 24, 26, 28, 30, 39, 40, 58, and 65 above, and further in view of Brockway. Strandberg, as modified, lacks details as to the structure of the implantable sensing device. Brockway discloses an implantable sensing device comprising an anchoring mechanism, wherein the mechanism may be a screw or tine (see entire document, especially figs. 3A-D of Brockway). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the structure of the sensor of Brockway as that of Strandberg, as modified, since Strandberg, as modified, teaches an implantable sensor, and Brockway describes an appropriate structure for such a sensor.

Regarding claims 50, 51, and 60 any portion of the anchoring mechanism is capable of passing through a septum wall of the heart. With further regard to claims 50 and 60, the language "means adapted for opening on at least one side of the septal wall and clamping said implantable device to the septal wall" fulfills the 3-prong analysis set forth in MPEP § 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. The corresponding structure for the means appears to be the umbrella structure shown in figure 5 and described on p. 13 of the instant specification. The stabilizer and housing of Brockway, as shown in figures 3A-D of Brockway is considered to be an equivalent of

the applicant's means for opening and means for clamping since one of ordinary skill in the art would have recognized the interchangeability of the stabilizer and housing of Brockway for the corresponding elements shown in the instant specification. Further, the stabilizer and housing of Brockway performs or is capable of performing the identical function specified in the claim in substantially the same way and produces substantially the same results as the corresponding element disclosed in the specification.

With further regard to claim 52, the anchoring mechanism comprises two umbrella shaped anchors adapted to be disposed on opposite sides of the atrial septum (see entire document, especially fig. 3D of Brockway).

With further regard to claims 53 and 60, the implantable sensing device comprises a larger portion and a smaller portion including a sensor, wherein the device is capable of be implanted such that the larger portion is located in the right side of the heart and the smaller portion in the left side so as to minimize the risk of thrombogenicity (see entire document, especially figs. 3A-D of Brockway).

With further regard to claim 54, he anchoring mechanism is a helical screw (see entire document, especially fig. 3A of Brockway).

With further regard to claim 55, the anchoring mechanism is a tine (see entire document, especially figs. 3A-D of Brockway), wherein the tine is capable or adapted to catch on a trabeculated area of the heart.

With further regard to claim 60, a pacing/ICD unit directly interrogates the sensing device (see entire document, especially col. 3, lines 1-13 of Strandberg).

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strandberg in view of Brockway, as applied to claims 49-55 above, and further in view of US Patent No. 6,636,769 to Govari et al. Brockway, as modified teaches the anchoring mechanism may be made form a memory metal (see entire document, especially col. 8, lines 47-49 of Brockway), but is silent as to the specific metal used. However, Govari teaches an implantable sensor having an anchoring mechanism made from a memory metal such as nitinol (see entire document, especially col. 6, lines 43-45 of Govari). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use nitinol as the material for the anchoring mechanism of Brockway, as modified, since Brockway, as modified, teaches using an anchoring mechanism, and Govari teaches nitinol as an appropriate memory metal for such an anchoring mechanism.

Claims 62, 63, 67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strandberg in view of Brockway, as applied to claims 2, 7, 8, 20, 22, 24, 26, 28, 30, 39, 40, 58 and 65, and further in view of US Patent No. 5,558,640 to Pfeiler. Strandberg, as modified, teaches the pacing/ICD unit directly interrogating the sensing device, rather than the sensing device transmitting data to the readout device, which retransmits data to the pacing/ICD unit. However, Pfeiler teaches a system wherein an implantable sensing device 9 transmits data to an external readout device 15, which retransmits data to an implantable medical device 11 (see entire document,

especially fig. 1; col. 3, line 63-67 of Pfeiler) and wherein the implantable sensing device communicates directly with the implantable medical device (see entire document, especially col. 4, line 66-col. 5, line 9 of Pfeiler). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the communication scheme of Pfeiler in place of that of Strandberg, as modified, as it would merely be the substitution of one known communication scheme for another, to yield the predictable result of the data being transmitted from the sensing device to the readout device and data being transmitted from the readout device to the pacing/ICD unit.

Regarding claim 63 and 68, the readout device and pacing/ICD unit perform at least one function of interrogation or powering of the at least one sensing device (see entirety of all documents, especially col. 3, lines 1-12 of Strandberg; col. 9, line 45-col. 10, line 25 of Brockway; col. 3, lines 63-67; col. 4, line 66-col. 5, line 9 of Pfeiler).

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway, as applied to claims 1, 5, 6, 9, 11, 12, 19, 21, 23, 25, 27, 29, 37, 38, 44, 57 and 69 above, and further in view of US Patent No. 5,067,491 to Taylor, II et al. Brockway lacks a coating, as recited in claim 70. However, Taylor, II teaches an implantable pressure sensor, wherein at least the sensing portion of the sensor is coated in a thin layer of parylene (see entire document, especially col. 2, line 27-col. 3 of Taylor, II). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the coating of parylene of Taylor, II on the sensing portion of the sensing device of Brockway, in order to extend the life of the sensor by protecting

the implant form damage by body fluids (see entire document, especially col. 1, line 47-22; col. 2, line 57-col. 3, line 7 of Taylor, II).

Claims 71 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strandberg in view of Brockway, as applied to claims 2, 7, 8, 20, 22, 24, 26, 28, 30, 39, 40, 58, and 65 above, and further in view of US Patent No. 5,067,491 to Taylor, II et al. Strandberg, as modified, lacks a coating, as recited in claim 70. However, Taylor, II teaches an implantable sensor, wherein at least the sensing portion of the sensor is coated in a thin layer of parylene (see entire document, especially col. 2, line 27-col. 3 of Taylor, II). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the coating of parylene of Taylor, II on the sensing portion of the sensing device of Strandberg, as modified, in order to extend the life of the sensor by protecting the implant form damage by body fluids (see entire document, especially col. 1, line 47-22; col. 2, line 57-col. 3, line 7 of Taylor, II).

Response to Arguments

Applicant's arguments filed 6/6/07 have been fully considered but they are not persuasive.

As to the Brockway reference, the applicants argue that the stabilizer 312D does not having any "clamping capability within the ordinary meaning of the term 'clam'", wherein the applicants have cited a dictionary definition of clamp as being "to fasten, strengthen, or brace with a clamp or clamps" and the noun "clamp" is "any of various

devices for clasping or fastening things together, or for bracing or strengthening parts". However, several dictionaries recite a definition of "clamp" as being "to hold tightly", where this definition is the broadest reasonable definition (see, for example, Merriam-Webster's Online dictionary or the Penguin English Dictionary). Additionally, the applicants have used "means plus function" language, wherein the structure of Brockway is shown to an equivalent of the corresponding structure described in the applicants' specification (see above rejection).

Allowable Subject Matter

Claim 31 is allowed. The allowability of claim 31 was addressed in previous Office actions filed 11/2/05 and 8/14/06.

Claim 66 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 61 would be similarly allowable if the rejection under 35 U.S.C. 112, 1st paragraph, set forth above, were also somehow overcome.

The following is a statement of reasons for the indication of allowable subject matter: Regarding claims 61 and 66, the primary reason for allowance is the inclusion of the sensing device being interrogated by the pacing/ICD unit and powered by the external unit, wherein the sensing device also has means for electromagnetic telecommunication and/or electromagnetic powering from the non-implantable readout device, in combination with all of the other limitations of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 3735